K041900

7 July 2004

AUG 3 1 2004

510(k) Summary of Safety and Effectiveness Information

Model No. / Name:	HC604 CPAP Humidifier
Classification Name:	Non-continuous ventilator (IPPB) - BZD Anesthesiology Devices, 21 CFR §868.5905 (Class II)
Predicate Devices:	Fisher & Paykel Healthcare, HC234 CPAP Humidifier, K040941

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92:

(a)(1) - (a)(3) Refer to information above and concluding this summary.

(a)(4) Description of the Device

The HC604 CPAP Humidifier is a non-invasive Continuous Positive Airway Pressure flow generator, incorporating a Heated Respiratory Humidifier and a heated respiratory breathing circuit.

The HC604 is comprised of two main functional units. One is a motorised fan assembly that provides positive air pressure, which can be adjusted from 4 to 20cm H_2O as prescribed by a physician. The fan speed is directly related to air pressure, and is controlled by software. The blower assembly output connects directly to a humidification chamber at the front of the device.

The second functional unit of the HC604 is a heated passover humidifier. The water is contained in a humidification chamber positioned on a heaterplate at the front of the unit. The chamber connects directly to the blower assembly via a port at the back of the chamber. Ambient temperature is monitored in order to reduce breathing tube condensation in cooler operating conditions. Condensation is further reduced by the heated breathing tube which connects to the outlet port on the fop of the unit.

(a)(5) Statement of the Intended Use

This HC604 CPAP humidifier is used to assist with patient breathing while sleeping, for the purpose of treating Obstructive Sleep Apnea (OSA). This is done by the delivery of Continuous Positive Airway Pressure (CPAP) in order to prevent airway obstruction. The addition of heated respiratory humidification to the device relieves the drying and irritating effects on the patient airways which may arise from use of a CPAP system. The HC604 CPAP humidifier is for use on adult patients.

(a)(6) Technological Characteristics Summary

The technological characteristics of the Fisher & Paykel Healthcare HC604 CPAP Humidifier are equivalent to the Fisher & Paykel Healthcare HC234 CPAP Humidifier.

The HC604 is equivalent to the HC234 in the following ways:

- Type (non-invasive Continuous Positive Airway Pressure flow generator, incorporating a Heated Respiratory Humidifier)
- Heaterplate power usage
- Control method (electronic)
- Ambient temperature sensor
- Operating pressure range (4 to 20 cm H_2O)
- Proportional start pressure algorithm
- User interface, with push buttons and an LCD display
- Manual altitude adjustment
- Double insulated design
- Reusable humidification chamber option

The HC604 differs from the HC234 in the following ways;

- Includes a heated breathing tube connected to the device, reducing condensation or "rain-out" to form in the tube
- Modified chamber design
- Some new materials used in the heated breathing tube
- Performance - increase in comparative humidity and temperature output

(b)(1) Discussion of the Non-Clinical Tests

Non-clinical testing of the HC604 CPAP Humidifier has been carried out covering mechanical, electrical and thermal safety, environmental conditions and electromagnetic compatibility, functional verification, and performance.

The HC604 meets the requirements of the IEC 60601-1 general electromedical and IEC 60601-1-2 EMC standards, and the relevant USA deviations to these in UL 60601-1. It complies with performance and safety requirements of the ISO 8185 and ASTM F1690 particular standards for humidifiers.

(b)(2) Discussion of the Clinical Tests

Clinical verification studies on the HC604 CPAP Humidifier were not required in order to demonstrate the safety, effectiveness, and performance of the device.

510(k) Summary continued - Fisher & Paykel, HC604 CPAP Humidifier

(b)(3) Conclusions Demonstrating Safety, Effectiveness and Performance

The testing carried out for the HC604 CPAP Humidifier indicates that it meets design and performance functional requirements. The proposed device meets the requirements of international and USA medical electrical equipment standards for safety, and key performance and safety requirements from particular standards for humidification systems.

This information indicates that the HC604 CPAP Humidifier is equivalent to the predicate device in terms of safety, effectiveness and performance.

signed: _____ date: 7/7/04

James Thompson
Fisher & Paykel Healthcare Ltd

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 1 2004

Mr. James Thompson
Regulatory Affairs Engineer-OSA
Fisher & Paykel Healthcare, Limited
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P.O. Box 14-348,
Panmure, Auckland,
NEW ZEALAND 1701

Re: K041900
Trade/Device Name: HC604 CPAP Humidifer
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: July 8, 2004
Received: July 14, 2004

Dear Mr. Thompson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

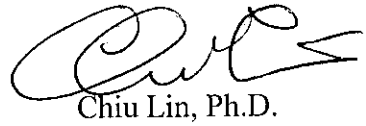
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

7 July 2004

510(k) Number: K041900

Device Name: HC604 CPAP Humidifier

INDICATIONS FOR USE:

The HC604 CPAP Humidifier is used to assist with patient breathing while sleeping, for the purpose of treating Obstructive Sleep Apnea (OSA). This is by the delivery of Continuous Positive Airway Pressure (CPAP) in order to prevent airway obstruction. The addition of heated respiratory humidification to this therapy relieves the drying and irritating effects on the patient airways, which may arise from use of a CPAP system.

The HC604 CPAP Humidifier is for use on adult, spontaneously breathing (non-ventilator dependant) patients at home or in the sleep laboratory.

Prescription Use ✓ and/or Over-the-Counter Use __

(Part 21 CFR 801 subpart D) (Part 21 CFR 801 subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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